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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAFFER, RICHARD R	
ART UNIT	**PAPER NUMBER**
3775	
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12/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,010	AUSTIN ET AL.	
	Examiner	Art Unit	
	Richard Shaffer	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,17-21,23-25,28-32,34,42-44 and 48-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25,28-32,34,42-44,48,50 and 52-54* is/are allowed.

6)☒ Claim(s) *1,5,17-21,23,24,34,49 and 51* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The cancellation of claim 3 in the response filed on April 4th, 2008 is acknowledged by the examiner. The previous 35 U.S.C. 112, 1st paragraph rejection is now withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 17, 34, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al (PCT Publication WO 00/40163) in view of Cooper (US Patent 4,836,485).

Faccioli et al disclose an external fixation apparatus (**Figures 1-11**) and a method of treating a skeletal condition with the apparatus comprising: fixing first member (**3**) by pins (**5**) to the tibia; a pivot arm (**20** and **35** together) having an upper portion with a ball end (**29, Figure 2**) and a lower portion with a prong end (**60** -- only one side defining a single prong); an asymmetric pin clamp (**40, 50**) coupled to and rotatable about the prong end through a lockable joint (interaction of **35** with **38**); the pin clamp fixed to a talus or calcaneus; and a push/pull mechanism (**35**) accessible externally for releasably coupling the pin clamp.

Faccioli et al disclose all of the claimed limitations except for carriage located within an internal recess defined by adjacent portions of the upper and lower portions with the carriage unit having a member for adjustment in a medial-lateral direction and a member for adjustment in the anterior-posterior direction.

Cooper teaches (**Figure 1**) that prior art arms can include an upper portion (**24**) and lower portion (**50**) having recesses (**66 and 68**) placed together to form an internal recess which receives a carriage (**74 with 80 and 82**). It would have been obvious to one having ordinary skill in the art at the time of invention to substitute a one-piece design for a multiple piece design in order to provide for an arm in a device with predictable results.

In regard to claim limitations directed towards movement along a medial-lateral direction and an anterior-posterior direction, the device as a whole can be moved in those directions and are held together by the components defined as being the carriage thereby meeting the claimed limitations.

Claims 18-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig (US Patent 5,827,282) in view of Lee et al (US Patent 5,405,347).

Pennig discloses a system (**Figures 1-9**) comprising: a first member (**22**, shown in **Figure 3**); a second member/pivot arm (**11, Figure 1**) having a shaft (**6**) extending transversely (**se Figure 2**) in a fixed relationship (**when 12 is tightened**) with a circumferential groove (**15**); a pin clamp (**1, Figure 1**) attachable and detachable from the shaft (**6**); the pin clamp having a first jaw (**3**) and a second jaw (**2**); a hole is located in the first jaw to receive the shaft (**6**); bolts (**4**) are received in order to bias the two jaws

together; a locator pin (**16**) is received within the groove to hold it into place; and the locator pin can be externally accessible for manual pushing or pulling to allow release of the shaft.

Pennig discloses all of the claimed limitations except for carriage located within an internal recess defined by adjacent portions of the upper and lower portions, the carriage having a worm gear with two threaded holes, a keybolt located in each of the upper and lower portions to control movement in two transverse directions relative the longitudinal axis and a bolt being received through the first and second jaws such that it interferes with the shaft and locks rotation of the pin clamp about the pivot arm.

Lee et al teach (**Figures 1-11; Column 1, Line 15-55)** that prior art devices attempted to accommodate for the situation when a surgeon realizes a section of fractured bone is out of alignment and is thus required to correct the fixation system by pivotally linked fixator rods. Lee et al did not disregard the pivotal movement, but stated that lateral movement was an important motion to allow a surgeon to realign the fixation device without removing bone pins. Lee et al used a carriage (**52**) with a threaded hole (**57**) in conjunction with a worm gear (**threaded portion of 46**) and keybolt (**head 48 of 46**) to provide for lateral movement. It would have been obvious to one having ordinary skill in the art to provide for lateral motion through the use of a worm gear in order to better assist a surgeon in realignment of the fixation device thereby avoiding bone pin removal and re-insertion.

Further, it would have been a matter of design choice to have bolt (**17**) pass through the first and second jaws (instead of just the first jaw) by allowing the second

jaw (**2**) to have an extended portion to also receive element (**17**) since applicant has not stated any criticality for the bolt to pass through two jaw members instead of merely one. The end result is the same; the bolt interferes with the shaft and locks rotation of the device. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Again, in regard to the new limitation of moving the portions of the arm in an anterior/posterior and medial/lateral direction are deemed disclosed and taught in the combination of Pennig and Lee et al since as a whole, components cause adjacent connected components to move with it.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig in view of Lee et al and in further view of Hoffman et al (US Patent Application 2002/0077629).

Pennig in view of Lee et al disclose all of the claimed limitations except for biasing elements that receive bolts (**4**) and are capable of biasing both jaws together. Hoffman et al teach (**Page 3, Paragraph 0028**) that coil springs (**10 and 10'**) holds the plates partially apart (loose connection) in order to ease installation of the bone pins in-between the jaws. Further, the springs would bias the jaws in alignment by being placed within their cavities and inherently would bias them slightly together (if pulled beyond their equilibrium point or if stretched and tied around the jaws). It would have been obvious to one having ordinary skill in the art at the time of invention to provide coil springs as taught by Hoffman et al to the device of Pennig in view of Lee et al in order to make it easier for the surgeon to install the bone pins within the pin clamp.

Allowable Subject Matter

Claims 25, 28-32, 34, 42-44, 48, 50 and 52-54 allowed.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1, 5, 17, 34, 49 and 51 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding claims 18-21, 23 and 24 filed April 4th, 2008 have been fully considered but they are not persuasive. As currently submitted, the limitation defining the movement of the device as explained in the current Office Action is insufficient to define the motion of the device over the prior art. As currently interpreted, anything attached to an object would read upon the language of being able to moving a first portion along an anterior-posterior direction as well as a second portion along a medial-lateral direction.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733